



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Smith, S.

Examiner: Isabella, D.

Serial No.: 10/630,562

Group Art Unit: 3738

Filed: July 30, 2003

Docket: 760-12 DIV/CON

For: HELICALLY FORMED  
STENT/GRAFT ASSEMBLY

Dated: October 7, 2004

Confirmation No.: 8643

I hereby certify this correspondence is being deposited with the  
United States Postal Service as first class mail, postpaid in an envelope,  
addressed to: Commissioner for Patents, Alexandria, VA 22313.

Dated: October 7, 2004

Signature: Barbara Thomas

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES  
TO OVERCOME A CITED PATENT UNDER 37 C.F.R. §1.131**

Sir:

1. I, Scott Smith, a citizen of the United States, residing at 6950 Country Road #10, Chaska, Minnesota 55318, is the inventor of the above-identified application.

2. At the time of the invention thereof and continuously to the present, I was and am an employee of SCIMED Life Systems, Inc., assignee of the present application. I submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to March 31, 1998, i.e., the effective date of U.S. Patent No. 6,063,111 to Hieshima et al. which was cited by the Examiner in an Office Action mailed, July 8, 2004.

3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention set forth in the claims of this application was completed in the United States before March 31, 1998, which is a date earlier than the U.S. filing date of the '111 Patent. Such completion being evidenced by conception of the invention prior to the effective date of the reference coupled with due diligence from prior to that date to the subsequent filing of the application. Exhibits A through I are submitted in support thereof. The Exhibits A through I are being submitted with their dates redacted. The actual document dates of Exhibits A and B are prior to March 31, 1998. The actual document dates of Exhibits C through I are after March 31, 1998, but prior to constructive reduction to practice date of July 2, 1999, i.e., the filing date of the parent Application No. 09/345,026, now U.S. Patent No. 6,364,904. A brief description of the documents being submitted are as follows:

- a. An invention disclosure (Exhibit A) bearing a date signed by myself, the inventor, prior to March 31, 1998, the filing date of the '111 Patent. The invention disclosure describes the invention as substantially set forth in the claims of the above-referenced application. The invention disclosure describes the use of a flat stent strip for use as a covered stent. The stent or stent strip is described being compressed against a layer or layers of flat ePTFE to form an assembly. This assembly is described as then being wrapped on a mandrel followed by laminating the components together. Alternately, the assembly may be laminated together prior to being wrapped on a mandrel.
- b. A letter prior to March 31, 1998 (Exhibit B) from Assignee's Patent Attorney to outside patent counsel enclosing the invention disclosure of Exhibit A and

requesting the preparation of a patent application.

- c. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit C) from outside patent counsel to Assignee's Patent Attorney reporting three application matters, including one for the parent (Docket No. 760-12, now U.S. Patent No. 6,364,904) of the above-referenced application, for the above-mentioned and related invention disclosures.
- d. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit D) from outside patent counsel to myself, the inventor, reporting the enclosure of drafts of three applications, including a draft of the parent of the above-referenced application.
- e. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit E) from Assignee's Patent Attorney to outside patent counsel reporting comments on the draft parent application.
- f. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit F) from outside patent counsel to Assignee's Patent Attorney reporting the preparation of three application drafts, including a draft of the above-mentioned parent patent application, for further review by myself, the inventor.
- g. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit G) from the Assistant to Assignee's Patent Attorney to outside patent counsel reporting additional comments relating to three draft

applications, including the above-mentioned parent application.

- h. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit H) from outside patent counsel to Assignee's Patent Attorney reporting the enclosure of three additional application drafts, including a draft of the above-mentioned parent application for review.
- i. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit I) from Assignee's Patent Attorney to outside patent counsel enclosing three executed patent applications, including the above-mentioned parent application, and requesting that the application be filed.


4. This declaration is being submitted in response to a Non-Final Office Action issued by the Examiner and therefore is believed to be timely filed.

5. The above-referenced exhibits establish a date of invention prior to March 31, 1998, the filing date of the '111 patent, and further establish diligence from that date to the filing date of the parent application, namely July 2, 1999.

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

*S/S*  
Dated: *Oct 28, 2004*

  
Scott Smith

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(973) 331-1700

SCIMED

Invention Disclosure Form

page 1 of \_\_\_\_

Descriptive Title of Invention: Spiral Wound Spiral StentInventor (s): Scott Smith Brian Brown

Date of Invention: \_\_\_\_\_

Date of First Drawing: \_\_\_\_\_

Date of First Written Description: \_\_\_\_\_

Date of Disclosure: \_\_\_\_\_

Internal: \_\_\_\_\_ To Whom: \_\_\_\_\_ (circle one) Written Oral

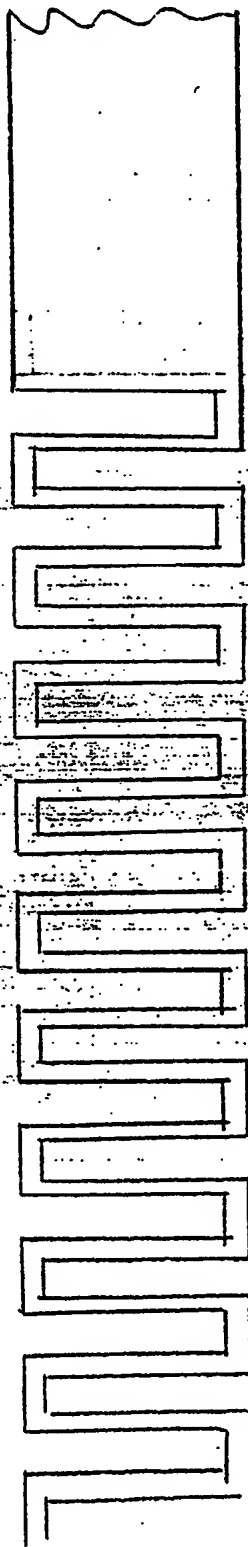
External: \_\_\_\_\_ To Whom: \_\_\_\_\_ (circle one) Written Oral

Description of Invention: Wound Spiral Slotted StentField of Application: StentsRelated SCIMED devices or concepts: Brian Brown's Stent Designs  
ArteriesDescription: Stent Formed From a Nitinol or other metal  
ribbon which is cut, wound, attached or welded, and is  
self expanding, bent set in expanded shape.Unique feature of invention: used readily available N.Ti ribbon (rolled wire)  
with minimal welding or bonding to produce a self-expanding stent  
Produced economically using flat slat techniques like etching, wire EDM or laserAdvantages of unique feature: cutting. these processes can be performed  
faster and with higher quality than with tubular shapes.  
Further more, welds can be positioned to minimize impact  
on expansion properties.



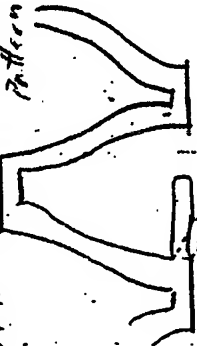
wrapped spiral 2" - zig slotted 5/8" x 1/2"

cut



cut

Alternate "open" pattern



Connects Board to Heat set into "cut" position

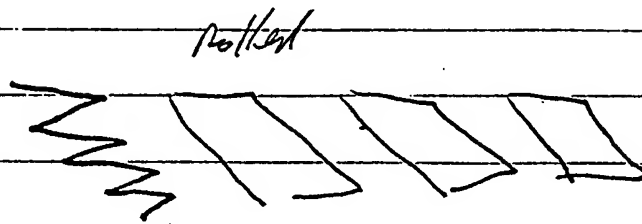
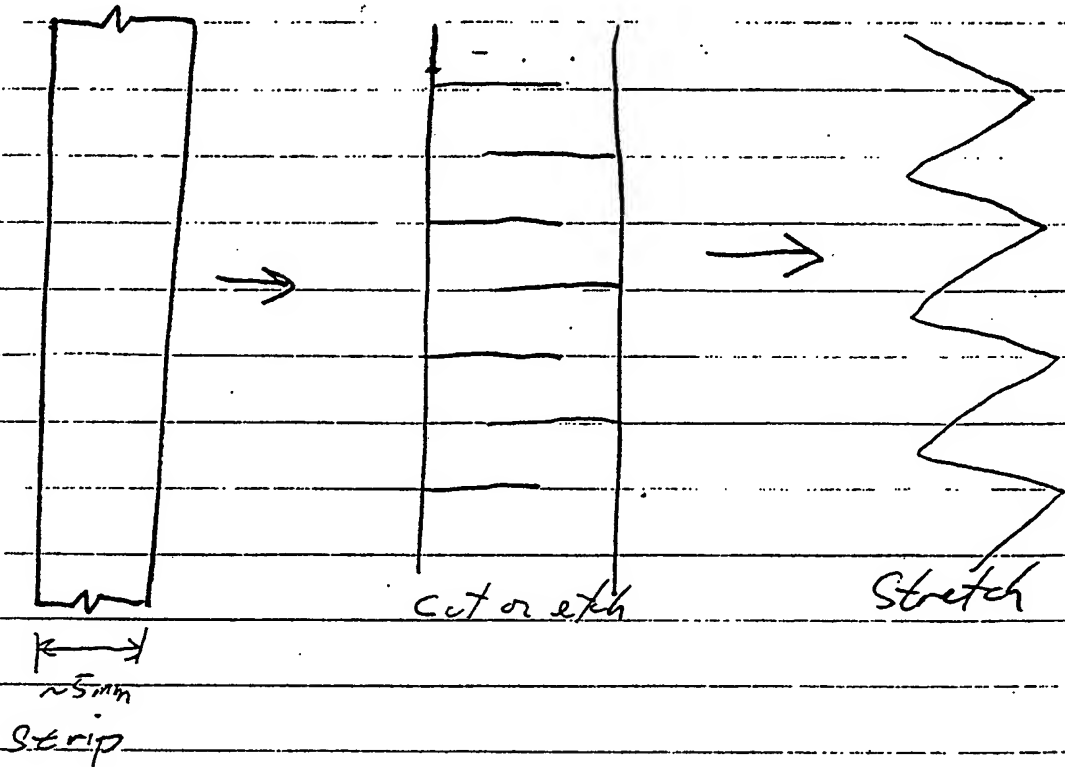
connector (weld on polymer)



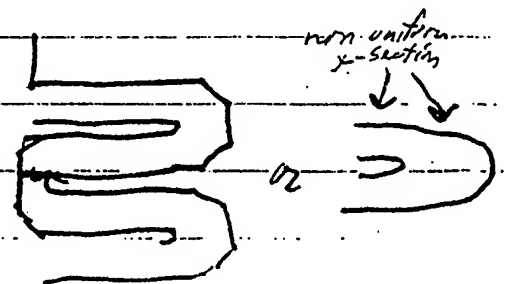
000927

000941

3. Since large, thin, flat sheet not readily available,  
use Long thin Strip to produce N.T. Sheet.



Possible specific design example:



Invented by: *Robert Smith*  
Witnessed by: *Charles E. [redacted]*



4. Connection or Articulation: Specific Patterns of Connection between Stent Segments result in improved (More Uniform, Lower Force, Less Kinking) Flexibility of Stents eg. Radliss 18 Stents

3 Connectors

each Segment offset by 3 Stents

Interm: 30 Stents

3 Connectors

each Segment offset by 5 Stents

Spiral Stents allow for Uniform Connector distribution using other #'s of Stents. Additionally, the Connector and Stents are distributed more uniformly Axially as well.

5. Covered Stents can be made from as follows:

1. <sup>wrap</sup> ~~wrap~~ a PTFE Membrane on Mandrel
2. wrap Stent or Load Stent on Mandrel over a PTFE
3. Apply more a PTFE over top.
4. heat & Compress to Bond Layers together

Alternatively,

1. Compress strip Stent (#3) between 2 layers of Flat a PTFE and heat, then wrap on Mandrel and re heat. Actually, 1<sup>st</sup> heat step not necessary.

Invented by: ~~Robert Smith~~ ~~Philip Smith~~

000941

56

outer PTFE

seam



6, seams can be multiple helixes to obtain still other contact distribution, use separate materials, or obtain different mechanical characteristics.

Invented by: *[Signature]*  
*[Signature]*

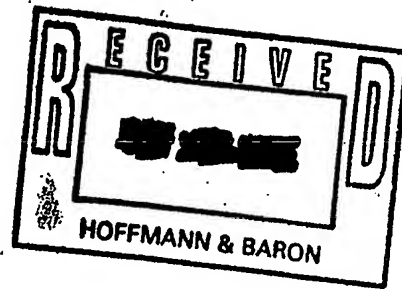
Witness:

*[Signature]*

**SCIMED**  
Boston Scientific Corporation

EXHIBIT B

SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566  
612-494-1700



[REDACTED]

Daniel A. Scola, Jr., Esq.  
HOFFMAN & BARON  
1055 Parsippany Boulevard  
Parsippany, NJ 07054

RE: Invention Disclosures 922, 927 and 941  
SCIMED File Nos.: SM-P0357-US01 and SM-P0406-US01

Dear Dan:

Under letters of [REDACTED] and [REDACTED] of this year, you received copies of the three above-mentioned disclosure forms. To insure that you have complete sets, another copy of each is enclosed. At this time, I would like you to begin preparing the two patent applications directed to these inventions. Invention Disclosure 927 and parts of Invention Disclosure 941 should be included in a patent application directed to Spiral Wound Stents (our file SM-P0357-US01). I have enclosed a copy of SCIMED's Application WO95/31945. Invention Disclosure 922 and the remainder of 941 are directed to an improved vascular stent graft device (our file SM-P0406-US01).

If you have any questions concerning these disclosures, feel free to contact me.

Sincerely,

Luke Dohmen  
Sr. Patent Attorney

LD:dl  
Enclosure

EXHIBIT C

HOFFMANN & BARON, LLP

ATTORNEYS AT LAW  
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\*\* ALSO ADMITTED IN NY  
\*\*\* ADMITTED IN NY & CONN ONLY  
□ ALSO ADMITTED IN CONNECTICUT  
+ ADMITTED IN WASHINGTON, D.C. ONLY  
• ALSO ADMITTED IN PENNSYLVANIA  
† ADMITTED IN PENNSYLVANIA ONLY  
∞ ADMITTED IN VIRGINIA ONLY

  
VIA FACSIMILE

Luke Dohmen, Esq.  
SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566

Re: SCIMED Patent Applications  
Our Dockets: 760-6; 760-7; 760-12

Dear Luke:

In response to your request of today, listed below is the information on the three (3) above-identified SCIMED patent applications:

Our Docket: 760-6  
SCIMED Reference: ID 927 and Part of ID 941  
File # SM-P0357-US01  
Title: Spiral Wound Stent  
Inventors: Scott Smith and Brian Brown

Our Docket: 760-7  
SCIMED Reference: ID 922  
File # SM-P0406-US01  
Title: Improved Composite Vascular Graft  
Inventor: Scott Smith

Our Docket: 760-12  
SCIMED Reference: ID 941  
File # SM-P0406-US01  
Title: Improved Stent/Graft Device  
Inventor: Scott Smith

**EXHIBIT D**

**HOFFMANN & BARON, LLP**

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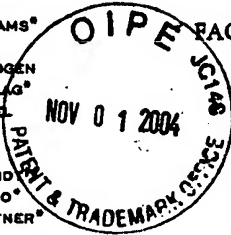
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ANTHONY E. BENNETT SAMIR R. PATEL\*  
KEVIN C. HOOPER\* WILLIAM D. SCHMID  
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GREGORY W. BACHMANN\* PATRICK J. HOFFNER\*



**VIA FACSIMILE**

Scott Smith  
SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566

Re: New Patent Applications  
Our Docket: 760-6; 760-7 and 760-12

Dear Scott:

Please find enclosed the application drafts for the above-referenced applications, which respectively correspond to the following inventions:

Our Docket: 760-6  
SCIMED Reference: ID 927 and Part of ID 941  
File # SM-P0357-US01  
Title: Spiral Wound Stent  
Inventors: Scott Smith and Brian Brown

Our Docket: 760-7  
SCIMED Reference: ID 922  
File # SM-P0456-US01  
Title: Improved Composite Vascular Graft  
Inventor: Scott Smith

Our Docket: 760-12  
SCIMED Reference: ID 941  
File # SM-P0456-US01

Mr. Scott Smith

Page 2

Title: Helically Formed Stent and Graft Assembly  
Inventor: Scott Smith

With respect to the IMPROVED STENT/GRAFT DEVICE (760-12) it is a partial draft with claims, figures, and background of invention included.

Please forward a copy of the SPIRAL WOUND STENT (760-6) application draft to Brian Brown. Dan Scola of this office will discuss the applications with you tomorrow.

In the meantime, should you any questions or comments, please communicate them with us at your convenience.

Very truly yours,



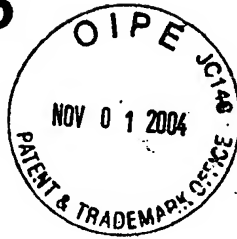
Mark E. Baron

MEB/mjm  
Enclosures

cc: L. Dohmen

**Boston  
Scientific  
SCIMED**

**EXHIBIT E**



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www.bscl.com

[REDACTED]

Daniel J. Scola, Esq.  
Hoffmann & Baron, LLP  
1055 Parsippany Blvd.  
Parsippany, NJ 07054

**PRIVILEGED & CONFIDENTIAL**

Re: U.S. Draft Patent Application for:  
***HELICALLY FORMED STENT AND GRAFT ASSEMBLY***  
Your File: 760-12  
Our File: SM-P0406-US01

Dear Dan:

Enclosed are our comments for the above-referenced draft patent application. Please contact me after you have had a chance to review the enclosed material.

Thank you for your assistance in this matter.

Very truly yours,

*Luke Dohmen /ed/*  
Luke Dohmen

Enclosure

LD/ld

**EXHIBIT F**

**HOFFMANN & BARON, LLP**

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RODERICK S.W. TURNER  
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NANCY A. BIRD\*  
JOHN S. SOPKO



Luke Dohmen, Esq.  
SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566

Re: New Patent Application For:  
SPIRAL WOUND STENT  
Our Docket: 760-6

New Patent Application For:  
IMPROVED COMPOSITE VASCULAR GRAFT  
Our Docket: 760-7

New Patent Application For:  
HELICALLY FORMED STENT/GRAFT ASSEMBLY  
Our Docket: 760-12

Dear Luke:

We have prepared the above-identified applications in final form for filing in the U.S. Patent and Trademark Office. We enclose copies of each application including formal papers for execution.

We ask that you arrange to have the inventors review the applications and execute the formal papers where indicated. Once the papers have been executed, please return the papers to us and we will promptly file the applications in the U.S. Patent and Trademark Office.

If during the review process, the inventors have any changes they wish to make to the applications, please have them make the changes in ink and initial and date the changes in the margin. In that manner, we can still file the application as executed.



## HOFFMANN &amp; BARON, LLP

ATTORNEYS AT LAW

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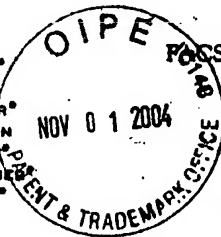
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+ SENIOR ATTORNEY

Luke Dohmen, Esq.  
SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566

Re: New Patent Application For:  
SPIRAL WOUND STENT  
Our Docket: 760-6

New Patent Application For:  
IMPROVED COMPOSITE VASCULAR GRAFT  
Our Docket: 760-7

New Patent Application For:  
HELICALLY FORMED STENT/GRAFT ASSEMBLY  
Our Docket: 760-12

Dear Luke:

Further to our previous correspondence, we have prepared the above-identified applications in final form for filing in the U.S. Patent and Trademark Office. The final form of these applications have been prepared incorporating the comments provided to us by the inventors. Included with each copy of the application are formal papers including a Combined Declaration and Power of Attorney as well as an Assignment of Invention form.

We ask that if you and the inventors find these applications to be acceptable, please execute the formal papers and return them to us. Upon receipt of the formal documents, we will arrange to file the applications in the U.S. Patent and Trademark Office.

Luke Dohmen, Esq.  
[REDACTED]

Page 2

If you or the inventors have any questions or comments or wish to discuss any portions of the application in further detail, please do not hesitate to contact us.

Very truly yours,

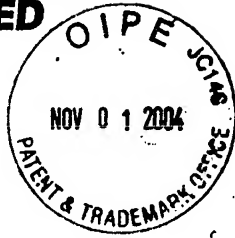


Salvatore J. Abbruzzese

SJA/mjm  
Enclosures

**Boston  
Scientific  
SCIMED**

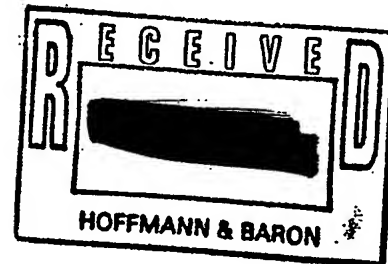
**EXHIBIT I**



Scimed Life Systems, Inc.  
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**VIA FEDERAL EXPRESS**

Salvatore J. Abbruzzese  
HOFFMAN & BARON  
1055 Parsippany Boulevard  
Parsippany, NJ 07054



RE: SPIRAL WOUND STENT  
Our File No.: SM-P0357-US01  
Your File No.: 760-6

IMPROVED COMPOSITE VASCULAR GRAFT  
Our File No.: SM-P0456-US01  
Your File No.: 760-7

HELICALLY FORMED STENT/GRAFT ASSEMBLY  
Our File No.: SM-P0406-US01  
Your File No.: 760-12

Dear Sal:

Enclosed are the executed patent applications with regard to the above-identified matters.  
Please place these applications on file with the United States Patent and Trademark  
Office as soon as possible.

If you have any questions, please call me.

Sincerely,

Luke Dohmen  
Sr. Patent Attorney

LD:dl  
Enclosures